

## **REMARKS**

### Status of the Claims

Claims 1, 3-15, and 17-21 are currently pending and under examination. Claims 2 and 16 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 19-21 have been added.

### Amendments to the Specification

The specification has been amended to replace “0,2 bar” with “0.2 bar” and “0,5 bar” with “0.5 bar” to comply with U.S. practice.

### Amendments to the Claims

Claim 1 has been amended to recite that extrusion occurs prior to formation of the liposome and that dispersion in an aqueous medium forms the liposomes. Representative support can be found in claim 2 as originally filed and in the specification at page 9, line 9 and at page 10, line 31.

Claims 1, 7, 8, and 10 have been amended to correct typographical errors.

Claims 19-21 are new. Representative support for new claims 19 and 20 can be found in claim 9 as originally filed. Representative support for new claim 21 can be found in claim 10 as originally filed.

The amendments to the claims do not add prohibited new matter.

### Declaration

Enclosed with this paper is a declaration for this U.S. application.

### Information Disclosure Statement

Applicants submitted an Information Disclosure Statement and PTO-1449 form on June 23, 2006, that disclosed three references. Applicants respectfully request that the Examiner consider the references in light of the pending application and initial and return to Applicants a copy of the PTO-1449 form as indication that the references have been considered.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 9 and 10 have been rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Applicants have amended claims 9 and 10 so that only one temperature or pressure limitation range is stated in the claims. It is therefore respectfully requested that this rejection be withdrawn.

Rejections under 35 U.S.C. 102(b)

A. Claims 1-7, 9-15, 17, and 18 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 5,556,580 (“‘580”).

The Office Action alleges that the ‘580 patent discloses a method of producing homogenous nanoscale liposomal material comprising extruding a composition comprising a cationic lipid by means of a compounder and dispersing the extruded composition in an aqueous medium. The Office Action also alleges that while the ‘580 patent does not disclose the elements of claim 3, the FRET properties are believed to be inherent.

The ‘580 patent does not disclose the claimed invention because the ‘580 patent discloses extrusion of preformed liposomes (*see, e.g.*, Example 3, column 7, line 31 discloses that the liposomes were extruded ten times; Example 4, column, 7, line 41 discloses that the resulting liposomes were processed by the method of Example 1 passing through a steel frit). Furthermore, the ‘580 patent discloses that “the liposomal material” in an aqueous phase is extruded (*see, e.g.*, column 3, lines 13-19). This indicates that the liposomes were formed prior to or during the extrusion process (*see, e.g.*, column 3, lines 18-19) in contrast to the present invention. Accordingly, the ‘580 patent does not disclose every element of the claimed method.

Since claim 3 is dependent upon claim 1, the ‘580 patent also does not anticipate claim 3. It is therefore respectfully requested that this rejection be withdrawn.

Rejection under 35 U.S. C. § 103(a)

Claim 8 is rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of the ‘580 patent.

The deficiencies of the ‘580 patent are discussed above. In view of the above arguments, claim 1, as amended, is not anticipated by the ‘580 patent. Accordingly, the ‘580 patent does not

disclose every element of claim 8 because claim 8 depends from claim 1 and includes all the features of claim 1. Furthermore, as discussed above, the differences between claim 1 and the '580 patent are significant. Thus, it is believed that claim 8 is not obvious over the '580 patent. It is therefore respectfully requested that this rejection be withdrawn.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicant respectfully requests entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,  
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